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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/818,943   | 03/28/2001  | Ulf Eriksson         | 1064/48487          | 9621             |
| 23911  | 7590        | 02/15/2005           | EXAMINER            |                  |
| CROWELL & MORING LLP<br>INTELLECTUAL PROPERTY GROUP<br>P.O. BOX 14300<br>WASHINGTON, DC 20044-4300 |             |                      | WHITEMAN, BRIAN A   |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1635                |                  |

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |                                      |  |  |
|--|--------------------------------------|--|--|
| <p align="center"><b>Advisory Action</b><br/><b>Before the Filing of an Appeal Brief</b></p> | <b>Application No.</b><br>09/818,943 | <b>Applicant(s)</b><br>ERIKSSON ET AL. |  |
|  | <b>Examiner</b><br>Brian Whiteman    | <b>Art Unit</b><br>1635                |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 31 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): the 112 first paragraph new matter rejection for claim 22.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: 5.
- Claim(s) objected to: None.
- Claim(s) rejected: 1, 6-9, 12, 14, 15, 18-20, 22-25 and 29.
- Claim(s) withdrawn from consideration: None.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_
13. ☒ Other: See Continuation Sheet.

Continuation of 11. does NOT place the application in condition for allowance because: The 112 first paragraph enablement rejection and 112 second paragraph rejection remain for the reasons of record.

With respect to applicant's argument that the fundamental flaw of the office action is that the enablement rejection is based on the reason that a different heart specific promoter would qualitatively alter the nature of the invention, the argument is not found persuasive because the claims are not specifically directed to heart specific promoters. Instead, the claims embrace a genus of a suitable promoter that is capable of directing polynucleotide expression in the heart.

With respect to applicant's argument that the citation or mentioning of the articles which discuss difficulties of animal cloning and the unpredictability in the "transgenic art" is irrelevant because none of these references states that the choice among similar promoters is determinative of the success of any animal cloning effort, the argument is not found persuasive for the reasons of record. See Wall (1996) and Houdebine (1994). In addition, there is no evidence of record to support applicant's argument that genus of promoters recited in the claims only embrace similar promoters (heart specific promoters).

With respect to applicant's argument that the opinions of Wall and Houdebine articles cited in the articles do not reflect the state of the art as of the filing date (2001), the argument is not found persuasive because the enablement rejection cites several references, including Wall and Houdebine, to support the unpredictability of producing transgenic mouse with a predicted phenotype. There is no evidence of record to support applicant's argument that, at the time of filing, producing transgenic mice with a particular phenotype was predictable. In addition, the application claims priority to a provisional application which was filed on 2000. Thus, the state of the art would be based 2000 and not 2001 as asserted by applicant.

With respect to applicant's argument that Wall does not indicate in any way that the difficulties and factors that contribute to the inefficiency of obtaining transgenic livestock relate to the choice among similar promoters, the argument is not found persuasive because the claims are not just limited to similar promoters (e.g., heart specific promoters). The claims encompass a genus of promoters that are capable to direct polynucleotide expression in the heart, which is not the equivalent of heart specific promoters. For example, the CMV promoter can direct expression of a transgene product in the heart, but the CMV promoter is not considered a heart specific promoter.

With respect to applicant's argument that there is no indication in Houdebine (which was published 1994 and not 1996, as correctly pointed out by applicant) that any difficulties in transgenic animal production is in any way determined by the choice among similar promoters and the page 275 of Houdebine cited by the examiner is misplaced because the passage relates to potential role of introns and not the choice among similar promoters, the argument is not found persuasive because the genus of the promoters encompassed by the claims is broader than a genus of similar promoters (e.g., heart specific promoters). The art of record indicates that the claimed genus could not be used by a skilled artisan without an undue amount of experimentation. There is no evidence of record to support applicant's argument that a genus of promoters capable of directing expression of the polynucleotide in heart is equivalent to a genus of heart specific promoters. In other words, the claims do not only read on similar promoters (e.g., heart specific promoters), the claims also read on promoters, which are not considered heart specific promoters, e.g., CMV, SV40, LTR, etc.

With respect to applicant's argument that there is no indication in Niemann that promoters having similar tissue specificity would cause such near opposite results and applicant cannot found the quoted text, the argument is not found persuasive for the reasons set forth above. In addition, the statement in the prior office action should not have been quoted because the statement was based on a summary of a paragraph and not a quote. See the bottom page 73 and top of page 74 of Niemann. Niemann teaches that transgenic pigs having different growth hormone gene constructs displayed different phenotypes.

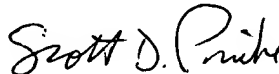
With respect to applicant's argument that Sigmund is not relevant to the current analysis because the random nature of transgene insertion is not specific to any particular promoter of choice, the argument is not found persuasive for the reasons of record and because Sigmund teaches that animals containing the same exact genetic manipulation exhibit profoundly different phenotypes.

With respect to applicant's assertion that factors that influence the "unpredictability" of transgenic animal production and the level of transgene expression etc. are well known and recognized in the art and the person with ordinary skill in the art always engage in experimentation which takes these factors into consideration and such experimentation are considered routine, the assertion is not found persuasive because other than the assertion, the applicant provides no evidence to support this assertion. Therefore, applicant's assertion is not compelling. See MPEP § 716.01(c).

With respect to applicant's argument that there is no reasonable basis to doubt that the claimed genus, relative to the exemplified species, would not work or would require undue experimentation, the argument is not found persuasive for the reasons set forth above.

With respect to applicant's argument against the 112 second paragraph rejection that promoters not capable of expressing the sequence are outside the scope of the claims, and the claims need not define any step with regard to such promoters, the argument is not found persuasive because the term "capable" does not indicate an active step. The term "capable" does not indicate whether or not the promoter was actively directing the expression of the polynucleotide sequence. Thus an active step is missing. An analogy for this reasoning follows: I am capable of playing basketball. This statement does not indicate whether or not I am playing basketball. Suggest deleting the phrase "capable of" on line 5 of claim 1.

Continuation of 13. Other: The Wilmut article (page 10 of applicant's argument) and the two exhibits (page 13 of applicant's argument) cited in the argument were not considered because the applicant failed to provide a showing of good and sufficient reason why the article and/or exhibits are necessary and not presented earlier.

  
**SCOTT D. PRIEBE, PH.D**  
**PRIMARY EXAMINER**